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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,198	08/10/2001	James Arthur Hoffmann	X12383N	6700

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	16

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/928,198	HOFFMANN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *104-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *104-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 February 2003, (Paper No. 12) has been entered.

Status of Application, Amendments and/or Claims

The amendment filed 21 February 2003 (Paper No. 13) has been entered in full. Claims 92-103 were cancelled. Claims 104-127 are under examination.

The Wijayaratne Declaration and Beals Declaration filed under 37 CFR 1.132 have been entered (21 February 2003, Paper No. 14).

The information disclosure statement filed 21 February 2003 (Paper No. 15) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

The cancellation of claims 92-103 make all rejections set forth in the previous Office Action (16 August 2002, Paper No. 9) moot. The Examiner will address Applicant's arguments as it applies to the Wijayaratne and Beals Declaration filed under 37 CFR 1.132 and pending claims 104-107.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 119 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection. The specification as originally filed does not provide support for the invention as now claimed: "a pharmaceutically acceptable formulation comprising urinary FSH or urinary variant FSH and benzyl alcohol in an aqueous diluent, wherein the rate of heterodimer loss at room temperature is about the same in the formulation as in a control formulation lacking benzyl alcohol".

Applicant's amendment, filed 21 February 2003 (Paper No. 13), asserts that no new matter has been added, however, the exact wording or connotation of the instant claims are not readily apparent from said sections. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 104 is rejected under 35 U.S.C. 102(b) as being anticipated by Hirai *et al.*, US Patent No. 4,659,696. Hirai teaches a pharmaceutical composition (column 1, lines 1-39). Examples of polypeptides used in the pharmaceutical composition include follicle-stimulating hormone (FSH) (column 3, lines 46-58 and claims). Hirai states, "to the aqueous pharmaceutical preparation for vaginal administration in accordance with the present invention there may be added, if necessary, preservative for example benzyl alcohol"(column 7, lines 44-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 105-111, 116-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai *et al.*, US Patent No. 4,659,696 in view of Skrabanja *et al.*, EP 0853 945 A1 (cited in IDS, reference #BF). The teachings of Hirai *et al.* are described above. Hirai does not explicitly state that FSH is human. Hirai does not teach multi-dose pharmaceutical products, urinary FSH, recombinant FSH or concentrations of FSH recited in the instant claims.

Skrabanja teaches a stable formulation comprising liquid FSH (abstract; page 3, lines 15-18, 35-38 and page 4, lines 11-13). FSH includes all forms including recombinant FSH (page 3, lines 51-54) urinary FSH (page 3, lines 44-54) and human FSH (page 3, lines 39-40; claim 10). Skrabanja teaches concentrations of FSH which overlap the concentrations in the instant claims (page 5, lines 9-14). Skrabanja teaches an article of manufacture comprising a vial or a pen-injector device. The formulation can be in the form of a cartridge for multiple use (page 5, lines 21-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Skrabanja regarding concentrations and various forms of FSH and preparations of pharmaceutical compositions and the teachings of Hirai regarding pharmaceutical compositions comprising FSH and benzyl alcohol to make the instant pharmaceutical invention. The motivation and expected

success is provided by Skrabanja and Hirai. Skrabanja teaches various concentrations of FSH and multi-dose articles of manufacture. Hirai teaches that benzyl alcohol can be used as a preservative in pharmaceutical formulations comprising FSH.

Claims 112-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai *et al.*, US Patent No. 4,659,696 and Skrabanja *et al.* EP 0853 945 A1 and further in view of Boime *et al.* US Patent No. 6,238,890 (cited in IDS, reference #AR). The teachings of Hirai and Skrabanja, are described above. None of the references teach the formulation comprising FSH variant of the formula α-subunit: (SEQ ID NO:5) and β-subunit: (SEQ ID NO:11)

Boime teaches the amino acid sequences of SEQ ID NO:5 and SEQ ID NO:11 (please see Appendix A and Appendix B). Boime states that the α and β subunits of the wild-type heterodimers or their variants or their fragments are covalently linked, optionally through a linker moiety (abstract). Boime describes single-chain forms of heterodimers or homodimers (column 4, lines 17-30 and 47-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Hirai and Skrabanja cited above to use the teachings of Boime to make the instant pharmaceutical invention. The motivation and expected success is provided by Skrabanja and Boime. Skrabanja teaches that different forms of FSH can be used in the multi-use liquid formulations including analogs, recombinant, modified glycosylated and other forms. Boime teaches that single chain forms are unique starting materials for identifying truncated forms with the activity

of the dimers and that using variants of the β subunit of FSH will also help identify agonists and antagonist of the glycoprotein hormone activity.

The Wijayaratne Declaration and Beals Declaration under 37 CFR 1.132 filed 21 February 2003 (Paper No. 14) is insufficient to overcome the newly made rejections of claims 104-107 under 35 U.S.C. 103(a) for the following reasons.

Wijayaratne states that the rate of FSH heterodimer loss at room temperature is about the same with benzyl alcohol as without, at both room temperature and at refrigerated temperature. Wijayaratne also states at 40°C, benzyl alcohol accelerates the heterodimer loss compared with the control lacking benzyl alcohol. He concludes by stating that he would expect the rate of heterodimer loss in the FSH formulation containing benzyl alcohol at room temperature to be greater than what was actually observed.

The Declaration of Wijayaratne is not found persuasive because Hirai *et al.*, US Patent No. 4,659,696 and Andya et al. US Patent No. 6,267,958 B1(cited in the Double Patent Rejection), teach pharmaceutical compositions comprising FSH (aqueous and lyophilized) and benzyl alcohol. In addition, the declaration does not demonstrate that the stability results were greater than those that would have been expected from the prior art to an unobvious extent. As was stated in the last Office Action, benzyl alcohol is known in the art as a preservative in pharmaceutical formulations. The declaration does not demonstrate that the results are of a significant advantage compared to the

control. The stability results of FSH and benzyl alcohol were no greater than the control (FSH alone) at room or refrigerated temperatures.

Beals describes the drug history of FSH and how the gonadotropin was stored. Some of the FSH products include: Humegon; urine purified FSH, LH, plus lactose and phosphate salts in a sterile lyophilized form (page 4). Metrodine; urine purified FSH and lactose in a sterile, lyophilized form (page 5). Fertinex; lyophilized FSH and lactose (page 6). Gonal-F; lyophilized recombinant FSH, sucrose, and phosphate salts (page 7). Follistim; recombinant hFSH contain sucrose, sodium citrate, and polysorbate 20 (page 8). Beals states that most if not all human chorionic gonadotropin (hCG) products on the market contained a preservative (usually benzyl alcohol) and were multi-dose products. HCG is also a heterodimeric gonadotropin, which like FSH, is comprised of an α-subunit and β-subunit. Human FSH and human GC are comprised of the same α-subunit. Beals concludes by stating that no FSH product was suitable for use as a multi-dose product because none contained a preservative.

This is found unpersuasive because Hirari *et al.*, US Patent No. 4,659,696 and Andya et al. US Patent No. 6,267,958 B1, teach formulations comprising FSH and benzyl alcohol. Furthermore, sucrose, sodium citrate, lactose, polysorbate 20 and phosphate salts, which Beals cites above, are all considered preservatives. Skrabanja *et al.*, EP 0853 945 A1, teaches stable preserved liquid FSH comprising preservatives (sucrose) in a multi-dose pharmaceutical product.

The Declarations of Wijayaratne and Beals are not persuasive based on the teachings of Hirai *et al.*, Andya et al. and Skrabanja *et al.* The history presented by

Beals demonstrates that FSH can be stably formulated with a preservative (sucrose, sodium citrate, etc). Human chorionic gonadotropin products, a heterodimeric gonadotropin like FSH, were provided as stable multi-dose products containing benzyl alcohol. The declarations do not demonstrate an unexpected property because benzyl alcohol is known in the art as a preservative. The claimed invention does not have a significance equal to or greater than the expected properties. There are no unexpected beneficial results. The stability results of FSH and benzyl alcohol were not significantly advantageous compared to the control (FSH alone).

The Examiner has cited literature, which teaches aqueous pharmaceutical preparations comprising benzyl alcohol and stable liquid multi-dose pharmaceutical products comprising FSH and preservatives. In addition, the Beals document cites FSH products with various preservatives. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 104-111 and 120-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-78 of copending Application No. 09/973918 in view of Andya *et al.*, US Patent No. 6,267,958 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application are drawn to a pharmaceutically acceptable formulation comprising FSH or FSH variant and benzyl alcohol.

The claims of application 09/973918 are drawn to an article of manufacture comprising a vial comprising lyophilized human FSH; an aqueous diluent comprising benzyl alcohol and packaging material comprising a label that includes instructions to reconstitute the FSH with the aqueous diluent.

Claim 104 as recited in the instant application embraces all forms and species of FSH (lyophilized, human). The claims in the instant application and in application 09/973918 recite pharmaceutical compositions comprising the same concentration of FSH, human FSH and FSH produced through the use of recombinant technology. The claims in the instant application and application 09/973918 recite the same preservative, benzyl alcohol. Lastly, the instant claims recite "sufficiently stable to provide a multi-dose pharmaceutical product". The claims of application 09/973918 recite "solution which may be held or used over a period of 24 hours or greater".

The claims in the instant application do not recite a specific concentration of benzyl alcohol. However, the adjustment of concentration ratios is deemed merely a matter of judicious selection and routine optimizations, which is well within the purview of the skilled artisan. In addition, the instant claims nor the claims of application 09/973918 disclose new and/or unexpected results because of benzyl alcohol concentrations. It is noted that written descriptions are not given patentable weight, since written material is a form of intellectual property protected by copyright, not patents. Furthermore, it would be obvious to provide written instructions regarding doses, storage, etc. with a pharmaceutical composition.

Andya teaches a stable lyophilized protein formulation which when reconstituted generates a stable multi-use formulation (column 1, lines 52-column 2, line 9). Andya teaches that the reconstituted formulation may be used as a multi-use formulation (column 2, lines 20-30). Andya teaches an article of manufacture comprising a container which holds a lyophilized mixture of a protein and instructions for reconstituting the lyophilized mixture with a diluent. The article of manufacture may further comprise a second container which holds a diluent (column 3, lines 22-31). Andya teaches follicle-stimulating hormone (FSH) as a suitable protein in the formulation (column 6, lines 44-50). Andya teaches that a preservative, such as benzyl alcohol, can be added to the diluent to reduce bacterial action in the reconstituted formulation, thus facilitating the production of a multi-use reconstituted formulation (column 9, lines 46-58).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 112-115 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 67, 68, 73, 74 of copending Application No. 09/973918 in view of Boime *et al.*, US Patent No. 6,238,890. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims in the instant application are drawn to FSH variants comprising α-subunit (SEQ ID NO:5) and β-subunit (SEQ ID NO:11) in a pharmaceutically acceptable formulation comprising benzyl alcohol, in an aqueous diluent.

The claims of application 09/973918 are generally drawn to an article of manufacture comprising a vial comprising lyophilized human FSH; an aqueous diluent comprising benzyl alcohol and packaging material comprising a label that includes instructions to reconstitute the FSH with the aqueous diluent.

The claims in the instant application and in application 09/973918 recite pharmaceutical compositions comprising FSH and benzyl alcohol. The instant claims recite "sufficiently stable to provide a multi-dose pharmaceutical product". The claims of application 09/973918 recite "solution which may be held or used over a period of 24 hours or greater". It would be obvious to provide written instructions regarding doses, storage, etc. with a pharmaceutical composition. A vial comprising FSH and a second vial comprising a preservative is an obvious employment of an old and well known way of storing pharmaceutical compositions and a matter of judicious selection which is well within the purview of the skilled artisan.

Boime teaches the amino acid sequences of SEQ ID NO:5 and SEQ ID NO:11.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 116-119 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 67, 68, 73, 74 of copending Application No. 09/973918 in view of Skrabanja *et al.*, EP 0853 945 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims in the instant application are drawn to FSH or FSH variants in a pharmaceutically acceptable formulation comprising benzyl alcohol.

The claims of application 09/973918 are generally drawn to an article of manufacture comprising a vial comprising lyophilized human FSH; an aqueous diluent comprising benzyl alcohol and packaging material comprising a label that includes instructions to reconstitute the FSH with the aqueous diluent.

The claims in the instant application and in application 09/973918 recite pharmaceutical compositions comprising FSH and benzyl alcohol. The instant claims recite "sufficiently stable to provide a multi-dose pharmaceutical product". The claims of application 09/973918 recite "solution which may be held or used over a period of 24 hours or greater". It would be obvious to provide written instructions regarding doses, storage, etc. with a pharmaceutical composition. A vial comprising FSH and a second vial comprising a preservative is an obvious employment of an old and well known way

of storing pharmaceutical compositions and a matter of judicious selection which is well within the purview of the skilled artisan.

Skrabanja teaches a stable formulation comprising liquid FSH (abstract; page 3, lines 15-18, 35-38 and page 4, lines 11-13). The formulation can be in the form of a cartridge for multiple uses (page 5, lines 21-45). FSH includes all forms including urinary FSH. Skrabanja teaches concentrations of FSH which overlap the concentrations in the instant claims (page 5, lines 9-14).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 104-115 and 120-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 141-152, 154, 156, 158 of copending Application No. 09/744431 in view of Andya *et al.*, US Patent No. 6,267,958 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims of the instant application are generally drawn to a pharmaceutically acceptable formulation comprising FSH or FSH variant and benzyl alcohol.

The claims of application 09/744,431 are generally drawn to a stable, pharmaceutically acceptable solution formulation suitable for multi-use comprising FSH

or an FSH variant, containing an alpha and a beta subunit and a preservative benzyl alcohol.

The claims in the instant application and in application 09/744,431 recite pharmaceutical compositions comprising the same preservative, benzyl alcohol and the same α-subunit (SEQ ID NO:5) and β-subunit (SEQ ID NO:11). The claims in the instant application and in application 09/744,431 both recite pharmaceutical compositions comprising human FSH, the same concentration of FSH and multi-dose pharmaceutical products.

Andya teaches a stable lyophilized protein formulation which when reconstituted generates a stable multi-use formulation (column 1, lines 52-column 2, line 9). Andya teaches that the reconstituted formulation may be used as a multi-use formulation (column 2, lines 20-30). Andya teaches an article of manufacture comprising a container which holds a lyophilized mixture of a protein and instructions for reconstituting the lyophilized mixture with a diluent. The article of manufacture may further comprise a second container which holds a diluent (column 3, lines 22-31). Andya teaches follicle-stimulating hormone (FSH) as a suitable protein in the formulation (column 6, lines 44-50). Andya teaches that a preservative, such as benzyl alcohol or m-cresol, can be added to the diluent to reduce bacterial action in the reconstituted formulation, thus facilitating the production of a multi-use reconstituted formulation (column 9, lines 46-58).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 116-119 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 141, 142, 153, 155-157 of copending Application No. 09/744431 in view of Skrabanja *et al.*, EP 0853 945 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims of the instant application are generally drawn to a pharmaceutically acceptable formulation comprising FSH or FSH variant and benzyl alcohol.

The claims of application 09/744,431 are generally drawn to a stable, pharmaceutically acceptable solution formulation suitable for multi-use comprising FSH or an FSH variant, containing an alpha and a beta subunit and a preservative benzyl alcohol in a cartridge and a method of treating infertility, comprising administering the instant formulation.

Skrabanja teaches a stable formulation comprising liquid FSH (abstract; page 3, lines 15-18, 35-38 and page 4, lines 11-13). The formulation can be in the form of a cartridge for multiple uses (page 5, lines 21-45). FSH includes all forms including urinary FSH. Skrabanja teaches concentrations of FSH which overlap the concentrations in the instant claims (page 5, lines 9-14). Skrabanja teaches the use of the composition to treat infertility (claim 15).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art of Record

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Rinella, US Patent No. 6,440,930 B1 teaches stable, soluble formulations comprising a medically useful peptide or protein, a hydrophobic preservative, and nicotinamide. The storage-stable soluble formulation is useful as a multi-use pharmaceutical product (abstract). The hydrophobic preservatives include benzyl alcohol (column 2, lines 49-60). Medically useful proteins include follicle-stimulating hormone (FSH) (column 3, line 64-column 4, line 40).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
April 14, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600